Sheila F. McShane
smcshane@gibbonslaw.com
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500
(973) 639-6482 – Fax

Of Counsel:
Matthew D. Powers
matthew.powers@weil.com
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, California 94065
(650) 802-3000
(650) 802-3100 – Fax

Nicolas G. Barzoukas
nicolas.barzoukas@weil.com
Rene Trevino
rene.trevino@weil.com
WEIL, GOTSHAL & MANGES LLP
700 Louisiana, Suite 1600
Houston, Texas 77002
(713) 546-5000
(713) 224-9511 – Fax

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CANCER RESEARCH TECHNOLOGY LIMITED and SCHERING CORPORATION,	:	
Plaintiffs,	:	Civil Action No. _____
v.	:	
ACCORD HEALTHCARE, INC.,	:	
Defendant.	:	

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

For their complaint, Plaintiffs allege as follows:

THE PARTIES

1. Cancer Research Technology Limited ("Cancer Research Technology") is a limited liability company organized and existing under the laws of the United Kingdom, having its principal place of business at Sardinia House, Sardinia Street, London, WC2A 3NL, England.

2. Schering Corporation ("Schering") is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 2000 Galloping Hill Rd., Kenilworth, NJ 07033-0530.

3. On information and belief, Accord Healthcare, Inc. ("Accord") is a company organized and existing under the laws of the State of North Carolina, having its principal place of business at 1009 Slater Rd., Suite 210B, Durham, NC 27703.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject mater of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

5. Venue is proper in this Judicial District under at least 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

6. Accord has consented to personal jurisdiction in this Judicial District for the purposes of this lawsuit.

7. This Court has personal jurisdiction over Accord because Accord has maintained continuous and systematic contacts with the State of New Jersey.

8. On information and belief, Accord is licensed with the New Jersey Department of Health and Senior Services as a seller of pharmaceuticals in the State of New Jersey.

9. On information and belief, generic drug products developed and manufactured by Accord and approved by the FDA are for sale and are sold in the State of New Jersey, including eleven (11) approved pharmaceuticals listed on the New Jersey Medicare formulary.

10. Accord has previously submitted to the jurisdiction of this Court in *Astrazeneca Pharmaceuticals LP, et al v. Accord Healthcare, Inc., et al*, Civil Action No. 3:08-cv-14804-JAP-TJB.

11. Accord has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims filed in this jurisdiction.

12. For all the reasons set forth above, this Court has jurisdiction over Accord.

THE PATENT-IN-SUIT

13. Cancer Research Technology is the owner by assignment of all right, title, and interest in United States Patent No. 5,260,291, entitled "TETRAZINE DERIVATIVES" (the "'291 patent"), which contains one or more claims covering the compound, composition and method of use of temozolomide ("TEMODAR®"). The '291 patent discloses and claims novel tetrazine derivative compounds, as well as methods for treating various cancers, including two types of brain cancers. A copy of the '291 patent is attached to this Original Complaint as Exhibit 1.

14. The '291 patent was duly and legally issued November 9, 1993, naming Edward Lunt, Malcolm F.G. Stevens, Robert Stone, Kenneth R.H. Wooldridge and Edward S. Newlands as the inventors. The '291 patent is set to expire on August 11, 2013, and pediatric marketing exclusivity for the '291 patent set to expire on February 11, 2014.

15. Schering has an exclusive license from Cancer Research Technology under the '291 patent to make, have made, use and sell temozolomide, the drug substance of TEMODAR®.

16. Cancer Research Technology and Schering have all rights to sue and recover for the infringement of the '291 patent.

BACKGROUND

17. Schering is the holder of approved New Drug Application No. 21-029, for the marketing of temozolomide for the treatment of adult patients with newly diagnosed gliobastoma multiforme and for the treatment of adult patients with refractory anaplastic astrocytoma. Schering markets and sells this compound and composition in TEMODAR® in 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, and 250 mg dosage forms. The 5 mg, 20 mg, 100 mg, and 250 mg dosage forms of TEMODAR® were approved by the FDA in August 1999. The 140 mg and 180 mg dosage forms of TEMODAR® were approved by the FDA in October 2006.

18. On information and belief, Accord has been and is engaging in activities directed toward infringement of the '291 patent by, *inter alia*, submitting an abbreviated new drug application ("ANDA") designated ANDA No. 20-1528 and seeking the FDA's approval to manufacture commercially its proposed product, a generic version of TEMODAR® named "Temozolomide Capsules" in 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, and 250 mg oral capsule dosage strengths, containing the active ingredient temozolomide (hereinafter referred to as the "Temozolomide Product"), before the expiration of the '291 patent.

19. In Accord's notice letter, dated October 11, 2010, entitled "Notice of Paragraph IV Certification," Accord has indicated that it intends to market its Temozolomide

Product before the expiration of the '291 patent. Plaintiffs received Accord's notice letter on or after October 13, 2010.

20. On information and belief, Accord's Temozolomide Product represents a composition that is intended to be used in a manner that would infringe the '291 patent.

21. On information and belief, Accord filed the ANDA because it seeks to enter the lucrative market that TEMODAR® has created with its beneficial and advantageous treatments of cancer.

22. On information and belief, Accord has been aware of the existence of the '291 patent, but nevertheless have been and are now infringing the '291 patent.

23. There has been and is now an actual controversy between Accord and Cancer Research Technology and Schering as to whether Accord infringes the '291 patent.

COUNT 1

24. Each of the preceding paragraphs 1 – 23 is incorporated as if fully set forth herein.

25. On information and belief, Accord filed the ANDA to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '291 patent, before the expiration of the '291 patent. On information and belief, Accord has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

26. On information and belief, when Accord filed the ANDA seeking approval to market a generic version of TEMODAR® before the expiration of the '291 patent, Accord was aware of the existence of the '291 patent and that the filing the ANDA constituted an act of infringement of that patent.

REQUESTED RELIEF

WHEREFORE, Cancer Research Technology and Schering respectfully request the following relief:

(a) That judgment be entered that Accord has infringed the '291 patent by submitting ANDA No. 20-1528;

(b) That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Accord, its officers, agents or attorneys or employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any chemical entity, therapeutic composition, and/or method of use covered by the '291 patent for the full terms thereof, including the applicable pediatric exclusivities, and from inducing or contributing to such activities;

(c) That an order be issued, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the ANDA be a date that is not earlier than the date of expiration of the '291 patent;

(d) Declaring this an exceptional case and awarding plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

(e) Awarding plaintiffs such other and further relief as this Court may deem just and proper under the circumstances.

Respectfully submitted,

Dated: November 19, 2010

By: s/ Sheila F. McShane

Sheila F. McShane
smcshane@gibbonslaw.com
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500
(973) 639-6482 – Fax

Of Counsel:
Matthew D. Powers
matthew.powers@weil.com
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, California 94065
(650) 802-3000
(650) 802-3100 – Fax

Nicolas G. Barzoukas
nicolas.barzoukas@weil.com
Rene Trevino
rene.trevino@weil.com
WEIL, GOTSHAL & MANGES LLP
700 Louisiana, Suite 1600
Houston, Texas 77002
(713) 546-5000
(713) 224-9511 – Fax

Attorneys for Cancer Research Technology Limited and Schering Corporation